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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,253

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Helen Francis-Lang

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EXAMINER

SHIN, DANA H

ART UNIT

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1635

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,253	Applicant(s) FRANCIS-LANG ET AL.	
	Examiner DANA SHIN	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 2-7 and 11-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2-13-06, 11-3-06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of claims 1 and 8-10 in the reply filed on June 2, 2008 is acknowledged. Applicant stated that the election is made with traverse. However, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

Currently, claims 1-25 are pending in the instant application. Claims 2-7 and 11-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Accordingly, claims 1 and 8-10 are under examination on the merits in the instant case.

Claim Objections

Claims 1 and 8 are objected to because of the following informalities: The abbreviated term, "UP" is not described in either initial or subsequent occurrence of the above claims. "UP" may mean a number of different subject matters. Since the instant specification defines "UP" as "uridine phosphorylase" on page 2, the abbreviated term, "UP" in the above claims will be construed as uridine phosphorylase. It is suggested that the abbreviation be defined at its first occurrence. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costa et al. (WO 03/052068 A2, applicant's citation) in view of Liu et al. (*Cancer Research*, 1998, 58:5418-5424, applicant's citation).

The claims are drawn to a method of identifying a candidate beta-catenin pathway modulating agent, comprising providing a PMO antisense oligomer targeted to uridine phosphorylase (UP) to an assay system and detecting the difference between the tested sample and the control (reference) sample in the assay system.

Costa et al. teach a method of identifying a candidate beta-catenin pathway modulating agent, comprising providing a PMO antisense oligomer that modifies beta-catenin to an assay system and detecting the difference between the tested sample and the control (reference) sample

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in the assay system. They teach that the assay system is a cell proliferation assay or expression analysis because beta-catenin signaling pathway is implicated in cell proliferation and apoptosis, especially in relation to tumor cells. They teach that one can also identify a modifier of beta-catenin by performing *C. elegans* or other animal mutant screening and identifying human orthologs/homologs by BLAST analysis. See pages 14-15, 20-26, 33-37, 41-42; claims 1 and 8-10. Costa et al. do not teach that UP is one of the beta-catenin modifier gene.

Liu et al. teach that human uridine phosphorylase (UP) activity is up-regulated in tumor tissues compared to normal tissues and suggest that blocking the UP activity may provide strategies for treating tumors. See the entire reference including Figure 6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to fully utilize the teachings and guidelines of Costa et al. as to how to identify a candidate agent that modulates beta-catenin signaling pathway, which would have led the skilled artisan to identify a UP PMO antisense oligonucleotide as the candidate agent.

One of ordinary skill in the art would have been motivated to make the claimed invention because Costa et al. explicitly taught the method of identifying a candidate beta-catenin pathway modulating agent comprising a PMO antisense oligonucleotide against a beta-catenin modifier gene. Since Costa et al. provided detailed guidelines and methodologies as to how to identify a beta-catenin modifier gene (e.g., *C. elegans* or other animal mutant screening followed by BLAST analysis, expression analysis, proliferation assays), and since UP activity was known to be significantly elevated in tumor cells compared to normal cells and was therefore implicated in cell proliferation as taught by Liu et al., one of ordinary skill in the art performing the method of Costa et al. would have necessarily identified UP as one of the beta-catenin modifier genes (for

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example, expression analysis showing UP is upregulated in tumor cells) and therefore would have used a UP PMO antisense oligonucleotide in an assay system (for example, the antisense oligonucleotide downregulates UP expression in tumor cells while a negative control does not) and therefore would have identified or verified that the UP PMO antisense oligonucleotide is indeed the beta-catenin pathway modulating agent. Since the knowledge and skills required to arrive at the claimed invention were within the technical grasp of one of ordinary skill in the art, and since Costa et al. provided the step-by-step guidelines for the claimed method (see claims 1 and 8-10 of Costa et al.), the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635